

## REMARKS

This application has been reviewed in light of the Final Rejection mailed March 11, 2009. Reconsideration of this application in view of the below remarks is respectfully requested. Claims 1 – 19 are pending in the application with Claims 1, 5 and 12 being in independent form. By the present amendment, Claims 1, 5, 9, 10, 12, 18 and 19 are amended.

Initially, Applicant notes that several informalities have been found in the claims, namely in Claims 9, 10, 18 and 19 “a annular-shape” instead of the more appropriate “the annular-shape”. The claims have been amended to correct the grammatical error.

Regarding amended Claims 1, 5 and 12, support for the features recited therein can be found throughout the specification. For example, FIG. 1A – 1B and 3A – 5 show annular recesses formed with sides and bottom surfaces having an interface between the sides and bottoms that is smoothly curved; and the formation of the annular-shaped recesses after formation of the cutting tip portion finds support on page 7, line 3 through page 8, line 10. Therefore, no new subject matter is introduced into the disclosure by way of the present amendment.

### **I. Rejection of Claims 1 – 11 under 35 U.S.C. § 112, Second Paragraph**

Claims 1 – 11 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Specifically, Claims 1 and 5 are allegedly unclear regarding the scope of the claimed invention. The Office Action asserts that it is unclear whether the claims are drawn to the sub-combination of the ultrasonic puncture needle or to the combination of the ultrasonic puncture needle and an ultrasonic endoscope.

In an effort to clarify the invention, Claims 1 and 5 are amended to recite that the ultrasonic puncture needle is "...adapted for insertion into a treatment tool insertion channel of an ultrasonic endoscope..."

Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to Claims 1 – 11 under 35 U.S.C. § 112, second paragraph.

## **II. Rejection of Claims 1 – 19 Under 35 U.S.C. § 103(a)**

Claims 1 – 19 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,238,336 issued to Ouchi in view of Japanese Publication No. JP 11-076254 (hereinafter, "Masatoshi") and further in view of U.S. Patent No. 5,759,154 issued to Hoyns.

In the present invention, a plurality of annular-shaped recesses formed on the needle tube are provided to a needle tube from a back surface of a cutting tip portion to a predetermined range on a surface of a tip portion, after the cutting tip portion is formed to the needle tube. The annular-shaped recesses are formed in an area excluding the cutting tip portion. Such a structure can eliminate problems arising from the cutting tip portion being partly chipped off during formation of the recesses, which can cause bending or breaking of the puncturing needle.

In contrast, as mentioned in previous responses, Masatoshi teaches a needle for puncture into lumen tissues, having a plurality of annular recesses formed on a surface of a tip portion of the tube. Masatoshi describes in its specification "many annular recesses 30 are provided on the surface of needle body 5 as shown Fig. 4, and the recesses have a cross-section shaped with sharp angle as shown in Fig. 5." However, Masatoshi does not disclose providing annular recesses from a back surface of the cutting tip portion to a predetermined range on a surface of a tip portion as in the present invention. Therefore, when the back surface of the cutting tip portion is opposed to

an ultrasound transducer at a shallow angle, the ultrasound does not return in the incident direction.

Furthermore in Masatoshi, since the cross-section of annular recesses is shaped with a sharp angle as shown in Fig. 5, when ultrasound 33 is emitted from ultrasound transducer 32 and reflected on the surface of needle body 5, majority of the echo signals are reflected to locations different from the emission locations, i.e., the ultrasound fails to return in the incident direction, as shown in Fig. 5.

On the other hand, Hoyns discloses needle 10 with a tip end portion having a plurality of reflection structures. Needle 10 is solid and has a sharp cutting portion formed by cutting the tip end portion of shaft 11 which is provided with a plurality of dents in advance. Thus, dents may be formed along an edge of the cutting portion, as shown in Fig. 1A. In Hoyns, since needle 10 is solid, the recesses formed to the cutting tip portion are not considered to cause decrease in needle strength. If the tip end portion of the needle tube of the present invention is previously provided with recesses and then cut to form the sharp cutting tip portion, the edge portion of the cutting tip portion would include parts of the annular recesses, thus partially chipping off the cutting tip portion. The resultant decrease in the strength of the cutting tip portion may cause bending and breaking, and thus decreased puncturability of the puncturing needle.

Ouchi teaches an ultrasound endoscope including: sheath 100 to be inserted into treatment tool insertion channel 13 of ultrasound endoscope; and needle tube 101 to be punctured into lumen tissues through the sheath. However Ouchi neither discloses nor suggests a plurality of staggered-array annular-shaped recesses provided in a predetermined range from a proximal part of the tip end to the tip end portion of the needle tube after the cutting tip portion is formed, as in the present invention.

In contrast, Applicant's ultrasonic puncture needle, as recited in Claims 1, 5 and 12, forms the annular-shaped recesses after the cutting tip is formed. As a result, the present invention, as recited in the claims, prevents weakening and deformation of the cutting tip portion caused by the situations described above. Instead, because the annular-shaped recesses are formed after the cutting tip portion is formed, the annular-shaped recesses are disposed on the cutting tip portion without alteration to their shape.

Moreover, the cited prior art references, taken alone or in any proper combination, fail to disclose that the annular-shaped recesses have flat surfaces on bottoms and sides with smoothly curving interfaces therebetween, as recited in Applicant's amended Claims 1, 5 and 12.

Therefore, for at least the reasons presented above, Claims 1 – 19 are believed to be allowable over the cited prior art references. Accordingly, Applicant respectfully requests withdrawal of the rejection with respect to Claims 1 – 19 under 35 U.S.C. § 103(a) over Ouchi in view of Masatoshi and further in view of Hoyns.

## CONCLUSIONS

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims presently pending in the application, namely, Claims 1 – 19 are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicant's undersigned attorney at the number indicated below.

Respectfully submitted,

/Thomas Spinelli/  
Thomas Spinelli  
Registration No. 39,533

SCULLY, SCOTT, MURPHY & PRESSER, P.C.  
400 Garden City Plaza - Ste. 300  
Garden City, New York 11530  
(516) 742-4343

TS/DAT:ab